

**IN THE UNITED STATES DISTRICT COURT FOR THE  
SOUTHERN DISTRICT OF WEST VIRGINIA**

THE CITY OF HUNTINGTON,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG  
CORPORATION, et al.,

Defendants.

Civil Action No. 3:17-01362  
Hon. David A. Faber

CABELL COUNTY COMMISSION,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG  
CORPORATION, et al.,

Defendants.

Civil Action No. 3:17-01655  
Hon. David A. Faber

**REPLY IN SUPPORT OF DEFENDANTS’ MOTION TO EXCLUDE  
CERTAIN EXPERT TESTIMONY OF KATHERINE KEYES**

Plaintiffs’ “Opposition to Motion to Exclude Testimony of Katherine Keyes, Ph.D.” (“Opp.”), ECF No. 1160, seeks to paint the issues before the Court as “technical” challenges that only trained epidemiologists could hope to understand. Not so. They are in fact some of the most fundamental issues in the case:

- In a suit claiming that distributors of *lawful* prescription opioids created a “nuisance” by causing opioid overdose deaths, is Keyes’ methodology—which ignores the role of *illegal* heroin and fentanyl in deaths that she opines were caused “directly” by prescription opioids—reliable?

- In a suit seeking an enormous monetary award for proposed treatment of persons with opioid use disorder (“OUD”), has Keyes used reliable principles and methods to estimate the size of the OUD population?

The answer to both questions is “no”—and thus Keyes’ opinions on both subjects are unreliable and inadmissible. Additionally, her opinion on the first issue should be excluded for failure to disclose the basis and reasons of her opinion, as required by Rules 26 and 37.

### **ARGUMENT**

#### **I. Keyes’ Opinion on Overdose Deaths Caused “Directly” by Prescription Opioids Is Unreliable and Inadmissible.**

In her recent deposition, Keyes admitted that she was aware that many of the deaths she classifies as caused “directly” by prescription opioids were coded by the medical examiner as involving heroin or illicit fentanyl.<sup>1</sup> Nevertheless, Keyes did not record the number of such cases because she did not consider it “informative to [her] methodology.”<sup>2</sup> In other words, because her goal was to attribute deaths to prescription opioids “directly,” Keyes purposefully ignored data showing how many of those overdoses involved decedents’ use of illicit substances that Defendants do not distribute at all:

Q. Okay. For purposes of determining a number of overdose deaths caused “directly” by prescription opioids, you weren’t interested in knowing how many of them also involved heroin?

A. That’s correct.<sup>3</sup>

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<sup>1</sup> Supp. App. 7 (Keyes 2d Dep. Tr. 18:10–20).

<sup>2</sup> *Id.*

<sup>3</sup> *Id.* at 8–9 (Keyes 2d Dep. Tr. 22:21 – 23:1); *see also id.* at 16 (Keyes 2d Dep. Tr. 53:16–17 (“A. Well, the 18 that involved prescription fentanyl could also involve illicit fentanyl.”)).

In other words, according to Keyes, every overdose death that involved a person using a prescription opioid was *directly caused* by use of the prescription opioid. And this is so, according to Keyes, even when the person was using heroin or illicit fentanyl at the time of the overdose. And even when it is completely unknown how much heroin or illicit fentanyl was in the decedent's system at the time of death—whether it was a trace amount or enough fentanyl to kill a horse.

Keyes' opinion is a departure from accepted scientific practice and, as such, unreliable. First, it is flatly contradicted by the Rule 30(b)(6) testimony of West Virginia's Chief Medical Examiner, Dr. Alan Mock, who explained how West Virginia death certificates record drugs in a decedent's system at the time of death. Dr. Mock testified that the policy of the Office of the Chief Medical Examiner is to include on each decedent's death certificate "[e]very drug" that shows up on a toxicology screen and has "a relevance."<sup>4</sup> The death certificate thus includes "all the drugs that are in a person's system," not just those drugs that "were at such a level that in and of themselves, they would have been lethal."<sup>5</sup> If a death certificate "lists an opioid—regardless of the opioid—it doesn't necessarily mean that that opioid in and of itself would have been lethal to that decedent."<sup>6</sup> And, most critically, Dr. Mock testified that when a West Virginia death certificate lists multiple drugs, "you could not say that one drug out of the mixture was responsible for the death ... you can't differentiate between which was the cause of death

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<sup>4</sup> *Id.* at 79–80 (Mock Dep. Tr. 205:10 – 206:20); *see also id.* at 74–77 (Mock Dep. Tr. 125:16 – 128:17). The Office of the Chief Medical Examiner handles all suspected drug overdose cases in West Virginia. *Id.* at 72 (Mock Dep. Tr. 64:4–8).

<sup>5</sup> *Id.* at 74–75 (Mock Dep. Tr. 125:16 – 126:2). Under this policy, the only drugs not listed on the death certificate are drugs like nicotine and caffeine that are exceedingly unlikely to contribute to an overdose. *Id.* at 79–80 (Mock Dep. Tr. 205:10 – 206:20).

<sup>6</sup> *Id.* at 75–76 (Mock Dep. Tr. 126:19 – 127:10).

ultimately.”<sup>7</sup> As Keyes acknowledges, the source of the drug overdose data upon which she relies is the information recorded on death certificates by the Office of the Chief Medical Examiner (i.e., Dr. Mock).<sup>8</sup>

Second, Keyes’ opinion that every overdose death involving a prescription opioid was directly caused by the prescription opioid (as opposed to heroin or illicit fentanyl or another drug) is completely at odds with the data practices of the Centers for Disease Control and Prevention (“CDC”). According to Keyes: “CDC and other authoritative sources correctly report overdose deaths that include prescription opioids as prescription-opioid deaths, even when additional drugs are identified.”<sup>9</sup> Keyes’ characterization of CDC’s reporting practices is wrong; the CDC does not identify any deaths as “prescription-opioid deaths,” as Keyes does in this case. Instead, the CDC—consistent with the policy and practice of the Office of the Chief Medical Examiner—identifies all substances “involved” in a drug overdose death, rather than identifying any substance as a “direct cause” or “indirect cause”:

Drug overdose deaths may involve multiple drugs; therefore, a single death might be included in more than one category when describing the number of drug overdose deaths involving specific drugs. For example, a death that involved both heroin and fentanyl would be included in both the number of drug overdose deaths involving heroin and the number of drug overdose deaths involving synthetic opioids other than methadone.<sup>10</sup>

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<sup>7</sup> *Id.*

<sup>8</sup> ECF No. 1056-3 (“App.”) at 106, 131–32 (Keyes Rpt. at 11, 36–37).

<sup>9</sup> *See id.* at 102, 150 (Keyes Rpt. at 7, 55 (citing, at reference 2, <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>)); *see also* Opp. 10.

<sup>10</sup> *See* Supp. App. 83 (CDC, Provisional Drug Overdose Counts, <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm> (last visited Nov. 19, 2020)).

Thus, Keyes' "coding" of the cause-of-death is a departure from accepted scientific practice. She misleadingly suggests that prescription opioids "caused" all overdose deaths in which it was found to be "involved"—including heroin-involved or fentanyl-involved deaths. Nothing in the CDC data (or the death certificate data on which the CDC data is based) supports that misleading suggestion. Keyes' departure from accepted practice is a hallmark of unreliability.

Finally, contrary to Plaintiffs' assertion, Defendants strongly challenge Keyes' unsupported opinion that overdose deaths would not have occurred "but-for" the presence of each individual drug identified on a death certificate.<sup>11</sup> Defendants' motion squarely challenged that opinion as lacking foundation, and Plaintiffs do not meaningfully respond.<sup>12</sup> Putting aside that Keyes is not a medical examiner or pathologist (i.e., lacks any credentials to determine cause of death), neither she nor Plaintiffs identify any scientific method or process that would allow her to opine as to which substances were "necessary conditions" to any given overdose. For example, in the case of an overdose decedent for whom a combination of cocaine, methamphetamine, prescription opioids, fentanyl, and alcohol are identified on a toxicology screen, Keyes has no basis to say that the overdose would have occurred even if one or more of those substances had been absent. Plaintiffs merely assert that each substance is a "necessary" cause of death because Keyes says so.<sup>13</sup>

All that Keyes can purport to know when multiple substances are identified on a death certificate is that all of those substances were identified in a toxicology screen of the decedent;

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<sup>11</sup> See Opp. 10.

<sup>12</sup> See Mot. at 5 ("Keyes lacks the expertise to say that, and her assertion is unfounded.").

<sup>13</sup> Opp. 10; *but see Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (*ipse dixit* opinions are properly excluded); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 603 (S.D.W. Va. 2013) (same).

whether any particular substance caused the death or whether a different combination of substances would or would not have been fatal is something about which she can only speculate. That is why—in addition to being incompatible with Dr. Mock’s authoritative testimony—her opinion that each listed substance was a “necessary condition” without which the death would not have occurred is utterly speculative. But as Plaintiffs correctly note, that speculation is the linchpin of Keyes’ opinion that every death *involving* a prescription opioid would not have occurred *but-for* the prescription opioid.<sup>14</sup> The Court should exclude that speculative opinion, along with the unfounded and misleading calculation to which it is attached.<sup>15</sup>

## **II. Keyes’ OUD Estimate Is Not the Product of Reliable Principles or Methods.**

Plaintiffs frame their defense of Keyes’ OUD population estimate around a familiar trope: Keyes is a Ph.D. epidemiologist, and Defendants’ counsel are not, therefore the Court has no choice but to take her (and Plaintiffs’ counsel’s) word for it that her methodology is reliable.<sup>16</sup> Of course, that circumstance exists in virtually every case in which scientific evidence is offered, and yet courts nevertheless are charged with determining whether the expert’s “testimony is the product of reliable principles and methods.”<sup>17</sup> The very case for which Rule 702 motions are informally named—*Daubert*—involved a dispute over the admissibility of expert opinions that

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<sup>14</sup> Opp. 10 (identifying this as Keyes’ sole basis for “treat[ing] all deaths in which a prescription opioid is listed on the death certificate as a death ‘directly attributable’ to prescription opioids”).

<sup>15</sup> Plaintiffs also assert that even if Keyes’ calculation is excluded, she and other experts nevertheless would be permitted to offer opinions “based on” it. Opp. 3 & n.4. It is unclear where Plaintiffs obtained such a misguided understanding. For the avoidance of doubt, Defendants’ motion seeks the exclusion in full of the opinions at issue in their motion.

<sup>16</sup> Opp. 18–19.

<sup>17</sup> Fed. R. Evid. 702(c).

included analysis of “epidemiological (human statistical) studies” by experts who held “impressive credentials,” but whose testimony ultimately was excluded.<sup>18</sup> Those credentials did not exempt the experts’ methodologies from scrutiny in *Daubert*, and neither do they exempt Keyes.<sup>19</sup>

**A. Plaintiffs Fail to Address a Fundamental Methodological Error in Keyes’ Opinion: Instability of the Baseline Population.**

Plaintiffs *concede* that a basic tenet of Keyes’ multiplier methodology is the existence of a “stable population” from which to extrapolate.<sup>20</sup> Their lone quibble on that issue is over the identity of the population that has to be stable—arguing it is the ““number of drug users entering or exiting the population.””<sup>21</sup> If Plaintiffs are correct that a precondition for the multiplier method is a stable population of the number of drug users, there are two fundamental problems with application of the method. First, Keyes uses her own multiplier method to estimate the “number of [opioid] drug users entering or exiting the population” from year to year—in other

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<sup>18</sup> See *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 582-83 (1993); *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) (“*Daubert II*”) (excluding Plaintiffs’ experts).

<sup>19</sup> Plaintiffs also regrettably infuse their defense of Keyes with a baseless and gratuitous smear of Defendants’ expert epidemiologist, whom Plaintiffs elected not to move to exclude. Opp. 20 & n.42. Contrary to Plaintiffs’ insinuation that Defendants’ expert has fabricated an association with Harvard Medical School, she identifies herself as “an Instructor in Medicine at Harvard Medical School” because that is what she in fact is. Harvard itself says so. See <https://connects.catalyst.harvard.edu/Profiles/display/Person/80422> (Harvard faculty profile identifying Defendants’ expert as an “Instructor in Medicine”) (last visited Nov. 19, 2020). The expert’s truthful acknowledgement that this faculty appointment does not constitute an employment relationship, Opp. 20 n.42, does not contradict any statement she has ever made. Moreover, contrary to Plaintiffs’ suggestion that Defendants’ expert is inexperienced in the epidemiology of opioid abuse, *id.*, she is currently retained by the Massachusetts Department of Public Health to study that very issue.

<sup>20</sup> Opp. 19.

<sup>21</sup> *Id.* (emphasis in original).

words, the **output** of Keyes’ analysis is the very thing that Plaintiffs contend must be known to be stable as a **precondition** for use of the multiplier method. Thus, it is impossible for Keyes to state that a precondition of population stability is known to be stable before conducting her analysis, and Plaintiffs’ argument is therefore fundamentally incoherent.

Second, even assuming that Keyes’ own results can be used to assess the stability of the population of opioid abusers, her results show there is no such stability. Indeed, Keyes’ results reflect wildly unstable patterns of individuals in Cabell County with OUD over time:

Year	Keyes’ OUD Estimate	Year to Year Difference
2011	6,359	+1,270
2012	3,763	-2,596
2013	7,692	+3,929
2014	6,677	-1,015
2015	8,257	+1,580
2016	8,403	+146
2017	10,643	+2,240
2018	8,252	-2,391 <sup>22</sup>

Keyes’ own results (unreliable as they are) imply that there are year-over-year changes of thousands of drug abusers entering or exiting the OUD population, including the population more than doubling (or falling by nearly half) in a given year. This is the population that Plaintiffs contend must be “stable” in order for Keyes’ multiplier method to have scientific validity,<sup>23</sup> and yet, by Keyes’ own estimation, it is anything but stable. Keyes’ opinion

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<sup>22</sup> See App. 136 (Keyes Rpt. 44).

<sup>23</sup> Opp. 19.



accordingly fails to satisfy the basic requirements of her methodology—requirements that Plaintiffs nowhere contest.

In short, Plaintiffs do not and cannot contest the methodological requirement to base such an estimate of the OUD population on a *stable* population of drug abusers. They simply ignore that their own expert’s estimates show that population is highly volatile and ill-suited to such a calculation. Accordingly, Keyes’ OUD estimate is not the product of reliable principles and methodologies. It is instead an estimate that exists in direct contradiction of the accepted principles of her field.

**B. Plaintiffs Concede That Illicit Fentanyl Has Become More Dangerous Since 2015, and Defend Keyes’ Opinions on Grounds Contained Nowhere in Her Expert Report.**

As Defendants demonstrated in their motion, Keyes’ estimate of the **2018** OUD population in Cabell County depends on her supposition that illicit fentanyl has not become more dangerous since 2015.<sup>24</sup> Plaintiffs do not disagree that Keyes’ estimate depends on that supposition. Neither do they contest Defendants’ evidence that certain fentanyl analogs available today, such as carfentanil, are vastly more dangerous than anything available in 2015.<sup>25</sup> Instead, they argue without support from Keyes that the increased risks of these dangerous

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<sup>24</sup> See Mot. 12–14 & n.36.

<sup>25</sup> Compare Mot. 14 n.36 with Opp. 22 n.44. Plaintiffs’ unsubstantiated statement that carfentanil appeared “before and after 2015,” Opp. 22 n.44, should not be credited. The DEA sources cited by Defendants demonstrate that this elephant tranquilizer was not present at all in the domestic drug market before 2016. See Mot. 14 n.36 (and sources cited therein). In contrast, Plaintiffs cite nothing to support their assertion that powerful synthetic opioids like carfentanil were available before 2015.

fentanyl analogs are balanced out by the alleged availability of other, less potent, fentanyl substitutes.<sup>26</sup>

Plaintiffs' arguments should not be credited. None of these contentions are found in Keyes' expert report or her depositions. Keyes does not, for example, opine (as Plaintiffs argue) that other fentanyl analogs "would have lowered, rather than raised, the rate of overdose deaths compared to fentanyl itself."<sup>27</sup> That claim is the invention of Plaintiffs' counsel who argue three pages earlier in the Opposition that legal counsel should not substitute their own interpretation of the epidemiological record for that of an expert.<sup>28</sup>

More fundamentally, Plaintiffs make no attempt to address other reasons why the risks posed by illicit fentanyl have increased since 2015—namely, that criminals are increasingly using fentanyl to adulterate heroin and also increasingly adulterating non-opioid substances like cocaine and methamphetamine.<sup>29</sup>

Having conceded that fentanyl analogs that emerged after 2015 are more dangerous than the fentanyl available as of 2015<sup>30</sup>—and simply ignored the increased incidence of adulteration of various drugs with fentanyl—Plaintiffs cannot tenably argue that the case mortality rate from 2015 is predictive of the population abusing fentanyl and its analogs in 2018, when overdose deaths are vastly higher due to the rapidly changing potency and morbidity of these illicit drugs of abuse. That opinion plainly is unreliable and should be excluded under Rule 702.

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<sup>26</sup> Opp. 22 n.44.

<sup>27</sup> *Id.*

<sup>28</sup> *Id.* at 19.

<sup>29</sup> See Mot. 14 n.36.

<sup>30</sup> Opp. 22 n.44.

**C. Plaintiffs’ Attempt to Corroborate Keyes’ OUD Estimate Is Meaningless Under *Daubert*.**

Plaintiffs argue that Keyes’ “OUD estimate based on the multiplier method” is admissible because it purportedly is “closely matched by the real-world OUD diagnoses in Cabell County/Huntington provided by Dr. Todd Davies, based on actual counts from local hospitals and clinics.”<sup>31</sup> Yet, the law is firmly established that the “focus” of a Rule 702 inquiry “must be *solely* on principles and methodology, not on the conclusions that they generate.”<sup>32</sup> Thus, even if Keyes’ estimate was supported by “real-world” observations, that could not cure any of the errors discussed above.<sup>33</sup>

**III. Keyes’ Undisclosed Methodologies Should Be Excluded Under Rule 37.**

Keyes testified that the revisions made to her report via her second errata on September 23 were the result of an *entirely new* methodology that she developed *after* her first deposition.<sup>34</sup> According to Keyes, “after thinking about it more” she “reconsidered” her approach and decided that projecting a “constant” rate of prescription fentanyl overdose deaths “rather than a ratio ...

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<sup>31</sup> *Id.* at 19–20 & n.40.

<sup>32</sup> *Daubert*, 509 U.S. at 595; *see also In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liability Litig. (No II)*, 892 F.3d 624, 631 (4th Cir. 2018) (same).

<sup>33</sup> In truth, however, Keyes’ estimate is far from credible based on real-world data. For example, a comprehensive peer-reviewed study conducted by, among others, a member of the Cabell-Huntington Health Department, recently concluded that “approximately 1900 [people who inject drugs of all types] reside in Cabell County.” Supp. App. 91 (Allen, et al., *Estimating the Number of People Who Inject Drugs in a Rural County in Appalachia* (AJPH Methods March 2019), at 447). Even if it were assumed that every one of those people had an OUD (notwithstanding that the study also included cocaine, methamphetamine, and other drugs, *id.* at 93 (Allen, et al. at 449 & tbl.3)), they still represent less than a quarter of Keyes’ estimate.

<sup>34</sup> *Id.* at 17–19 (Keyes 2d Dep. Tr. 61:8 – 63:19); *see also id.* at 4–6 (Keyes 2d Dep. Tr. 13:19 – 15:5) (same).

might be a more accurate reflection of the prescription fentanyl contribution.”<sup>35</sup> Using this “constant” approach, Keyes adds three additional prescription opioid deaths per year from 2013 to 2018, representing what she calculates as Cabell County’s average fentanyl overdose deaths from 1999 to 2012. (As explained below, however, this supposed “average” is the product of assumptions rather than a direct count.)

This change in Keyes’ methodology required her to make different assumptions than those disclosed in her report. For example, Keyes’ original methodology posited that prescription fentanyl overdose deaths could be estimated as a proportional share of all fentanyl overdoses (prescription and illicit) after 2013.<sup>36</sup> That opinion—flawed and inadmissible as it was<sup>37</sup>—tied Keyes’ estimate of 2013 to 2018 prescription fentanyl overdose deaths to overdoses actually occurring during those years. By contrast, her new opinion is based entirely on her calculation of the average number of fentanyl-involved overdose deaths before 2012, extrapolated to occur every year from 2013 forward.<sup>38</sup> Keyes makes this assumption notwithstanding the fact that in the years immediately prior to 2013, there was on average only *one* fentanyl-involved overdose death in Cabell County, and in two of those years there were *none at all*.<sup>39</sup> Keyes thus projects for 2013 and later years an assumed level of fentanyl-involved overdoses that far exceed the last several years in which the number of cases was known.

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<sup>35</sup> *Id.* at 18, 19 (Keyes 2d Dep. Tr. 62:2–11, 63:11–19).

<sup>36</sup> *See* Mot. 7–9, and sources cited therein.

<sup>37</sup> Plaintiffs fail to contest, and therefore tacitly concede, the inadmissibility of that former opinion. *See* Opp. 13.

<sup>38</sup> Supp. App. 21–23, (Keyes 2d Dep. Tr. 65:1 – 67:18); *id.* at 63 (Keyes 2d Dep. Ex. 6).

<sup>39</sup> *Id.* at 11, 13, 58–60 (Keyes 2d Dep. Tr. 41:5–14, 50:1–5, 105:11 – 107:14).

While Keyes asserted in her deposition that she considers this changed methodology to be reliable, she concedes that even to this day she has not made the requisite written disclosure of the “basis and reasons” for this aspect of her opinion:

Q. Where in your second errata served after your deposition can I find a discussion of the reasons and basis for that methodology?

A. The numbers are provided in the second errata, but a narrative description is not provided.

Q. And so it’s fair to say in terms of any written disclosures to the Defendants, you’ve not provided anywhere a discussion of this methodology or the reasons and basis for it, correct?

A. I have — Sorry. I have provided updated numbers and a data file, and that’s all I have provided thus far.

Q. Just the results, right?

A. The results.<sup>40</sup>

Keyes’ second changed methodology involves her treatment of data that is “suppressed” in the CDC’s WONDER database. As she explained, when there are fewer than ten death certificates responsive to a given query, the CDC’s database provides a non-specific answer that indicates the true number is anywhere from “0” to “9”—a phenomenon referred to as data suppression.<sup>41</sup> Because of data suppression, Keyes was unable to isolate an actual count of either the prescription opioid-involved or the fentanyl-involved overdose deaths in Cabell County in five years: 1999, 2000, 2001, 2003, or 2005. Accordingly, Keyes originally included

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<sup>40</sup> *Id.* at 61 (Keyes 2d Dep. Tr. 108:5–19) (objection omitted); *but see* Fed. R. Civ. P. 26(a)(2)(B)(i) (experts must disclose “a complete statement of all opinions the witness will express *and the basis and reasons for them*”); *id.* R. 26(e)(2) (“For an expert whose report must be disclosed under Rule 26(a)(2)(B), the party’s duty to supplement extends both to information included in the report and to information given during the expert’s deposition.”). All emphases are added unless otherwise noted.

<sup>41</sup> Supp. App. 30–33 (Keyes 2d Dep. Tr. 74:8 – 77:8).

each of those yearly totals in her workpapers with the notation “NA” for “not available.”<sup>42</sup> For those years with a specific number, Keyes originally identified 25 fentanyl-involved overdose deaths in Cabell County from 1999 through 2012, with no individual year having more than six.<sup>43</sup>

But, for the calculation in her second errata, Keyes treated those suppressed (“NA”) entries differently; she replaced them with numbers. Specifically, she replaced certain of the “NA” entries with the number “5,” ostensibly because she considers that to be the mid-point in the possible values between 0 and 9.<sup>44</sup> However, other “NA” entries—those representing fentanyl-involved overdose deaths—were not replaced in the same manner. Instead, Keyes filled in those entries by subtracting the newly-changed “suppressed” entries (i.e., subtracting 5) from the total overdoses for that year, and treating the amount left over as the fentanyl-involved total.<sup>45</sup> As a result of this changed methodology, Keyes purports to identify 17 additional fentanyl-involved deaths from 1999 to 2012 that were nowhere visible to her in the data.<sup>46</sup>

As with the prior change in methodology, Keyes again acknowledged that she has not provided any written disclosure of the “basis and reasons” for this revised approach:

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<sup>42</sup> *Id.* at 35–36 (Keyes 2d Dep. Tr. 79:6 – 80:21); *id.* at 65–66 (Keyes 2nd Dep. Ex. 10, at Columns G & J, Rows 43–49).

<sup>43</sup> *Id.* at 37–41 (Keyes 2d Dep. Tr. 81:10 – 85:1).

<sup>44</sup> *Id.* at 44–47 (Keyes 2d Dep. Tr. 88:11 – 91:7); *id.* at 63–66 (Keyes 2nd Depo Exs. 6, 10).

<sup>45</sup> *Id.* at 47–48 (Keyes 2d Dep. Tr. 91:8 – 92:7).

<sup>46</sup> *Id.* at 51–53 (Keyes 2d Dep. Tr. 95:5 – 97:6 (2001 estimate of 7 deaths)); *Id.* at 53–56 (Keyes 2d Dep. Tr. 97:18 – 100:9 (2003 estimate of 10 deaths)). Notably, these estimates are each individually *higher* than any year for which Keyes could directly count the number of overdoses in the same category. *Id.* And the entry for 2003 is necessarily wrong, because if there had been ten fentanyl-involved overdose deaths, the number published in the CDC WONDER database would not have been suppressed.

Q. And how about your methodology for replacing suppressed data in some columns with the number five, where in your report can I find an explanation of your reasons and basis for making that adjustment when the data is suppressed?

A. I don't think it's described in the report.

Q. Is it described anywhere in your [first or] second errata?

A. No.<sup>47</sup>

Finally, Keyes admitted that as a result of the changes reflected in her second errata, a different opinion presented in her expert report is no longer accurate, but has not been updated or corrected. Specifically, Keyes' Figure 8 purports to show overdose death rates from prescription opioids in Cabell County, West Virginia, and the United States as a whole.<sup>48</sup> However, those rates are based on Keyes' earlier (higher) estimates of the overdose deaths caused directly by prescription opioids; Keyes admitted that were she "today to sit down and reconstruct [her] Figure 8" her estimates would be different.<sup>49</sup> Those different estimates are not contained within Keyes' second errata, and neither have they been disclosed anyplace else.<sup>50</sup>

Keyes' revised opinion should be excluded for all of these reasons. Rule 26 requires a retained or specially employed expert witness to furnish a report containing "a complete statement of all opinions the witness will express *and the basis and reasons for them*["]."<sup>51</sup> When an expert or party concludes that the disclosure made in that report is "incomplete or

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<sup>47</sup> *Id.* at 61–62 (Keyes Dep. Tr. 108:20 – 109:7).

<sup>48</sup> App. 130 (Keyes Rpt. 35).

<sup>49</sup> Supp. App. 28 (Keyes 2d Dep. Tr. 72:4–14).

<sup>50</sup> *Id.* (Keyes 2d Dep. Tr. 72:17–20 ("Q. Is the information ... that would be more accurately plotted in Figure 8 today, are those numbers stated in your second errata? A. No.")).

<sup>51</sup> Fed. R. Civ. P. 26(a)(2)(B)(i) (emphasis added).

incorrect,” then the expert has the duty to “supplement or correct” the report “in a timely manner.”<sup>52</sup> If this supplementation is not made, then “the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless.”<sup>53</sup>

Keyes has not provided the disclosure mandated by Rule 26, and that failure is neither harmless nor substantially justified. As the Fourth Circuit has held, “Rule 37(c)(1) does not require a finding of bad faith or callous disregard of the discovery rules.”<sup>54</sup> “[E]xcluding evidence only when the nondisclosing party acted in bad faith would undermine the basic purpose of Rule 37(c)(1): preventing surprise and prejudice to the opposing party.”<sup>55</sup> “And, requiring proof that the nondisclosing party acted in bad faith would improperly shift the burden of proof away from that party on the exclusion issue.”<sup>56</sup>

Plaintiffs argue that there can be no “prejudice whatsoever because Defendants have had the opportunity to depose Dr. Keyes after receiving the Second Errata.”<sup>57</sup> Yet, contrary to this suggestion, “the ability to simply cross-examine an expert concerning a new opinion at trial is not the ability to cure[.]”<sup>58</sup> The “rules of expert disclosure are designed to allow an opponent

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<sup>52</sup> *Id.* R. 26(e)(1)(A), 26(e)(2).

<sup>53</sup> *Id.* R. 37(c)(1).

<sup>54</sup> *Southern States Rack & Fixture, Inc. v. Sherwin-Williams Co.*, 318 F.3d 592, 596 (4th Cir. 2003).

<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

<sup>57</sup> Opp. 16.

<sup>58</sup> *Southern States Rack & Fixture*, 318 F.3d at 598 (quoting the affirmed opinion of the District Court).



to examine an expert opinion for flaws and to develop counter-testimony through that party's own experts.”<sup>59</sup>

As in *Southern States Rack & Fixture*, Plaintiffs' ongoing refusal to supplement Keyes' report with the basis and reasons for her “*current methodology*”<sup>60</sup> prejudices Defendants' ability to prepare responsive expert testimony. And there can be no justification for Keyes' ongoing refusal to comply with Rule 26's supplementation requirement. She changed her mind about an opinion nearly two months ago. Defendants pointed out the inadequate supplementation some six weeks ago. Nevertheless, Plaintiffs and Keyes continue to operate as though Rule 26 does not apply.

### **CONCLUSION**

For the foregoing reasons, Defendants' motion should be granted.

Dated: November 19, 2020

Respectfully submitted,

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<sup>59</sup> *Id.* (quoting the affirmed opinion of the District Court).

<sup>60</sup> Opp. 13 (emphasis in original).

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**CERTIFICATE OF SERVICE**

I hereby certify that on November 19, 2020, the foregoing *Reply in Support of Defendants' Motion to Exclude Certain Expert Testimony of Katherine Keyes* was filed using the Court's CM/ECF system, which will serve notification of such filing on all counsel of record.

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